

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,001	06/03/2002	Yinghui Dan	MONS:130US	7199
46795 7590 02/12/2007 FULBRIGHT & JAWORSKI, LLP 600 CONGRESS AVENUE, SUITE 2400			EXAMINER	
			ROBINSON, KEITH O NEAL	
AUSTIN, TX 78745			ART UNIT	PAPER NUMBER
			1638	
			· · · · · · · · · · · · · · · · · · ·	
SHORTENED STATUTORY	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MON	NTHS	02/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

	Application No.	Applicant(s)			
000 4 4 0	10/064,001	DAN ET AL.			
Office Action Summary	Examiner	Art Unit			
	Keith O. Robinson, Ph.D.	1638			
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING C  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONEI	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 11 L	Responsive to communication(s) filed on <u>11 December 2006</u> .				
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Thi	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3) Since this application is in condition for allowa	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)  Claim(s) 1-16 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 1-16 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) ☐ The specification is objected to by the Examin 10) ☑ The drawing(s) filed on 22 August 2005 is/are:  Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the E	a)⊠ accepted or b)⊡ objected to drawing(s) be held in abeyance. See action is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date  S Patent and Trademark Office.	(PTO-413) te atent Application				

Art Unit: 1638

#### **DETAILED ACTION**

Page 2

#### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 11, 2006 has been entered.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action mailed March 18, 2005. The amendment of claim 1, filed December 11, 2006, has been received and entered in full.
- 3. Claims 1-16 are under examination.

## Response to Arguments

4. Applicant's claim amendment, see 'Claim Amendments', page 2, filed December 11, 2006, with respect to the 35 USC § 112, second paragraph rejection of claims 12 and 14 on page 2 of the Office Action mailed August 10, 2006, has overcome the rejection. The rejection has been withdrawn.

## Claim Rejections - 35 USC § 102

5. Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Fry et al (U.S. Patent 5,631,152). The rejection is repeated for the reasons of record as set forth in the Office Action mailed August 10, 2006 (see pages 2-3). Applicant's

Art Unit: 1638

arguments, filed December 11, 2006, have been fully considered but are not persuasive.

Applicant argues that the action fails to make a *prima facie* case for anticipation because the cited reference does not expressly or inherently disclose all of the claim elements (see page 5, paragraph 'B' in the 'Remarks' filed December 11, 2006).

This is not persuasive. As stated in the previous Office Action mailed November 22, 2005, Fry et al disclose a method for producing transgenic wheat comprising culturing explants, introducing exogenous DNA via bombardment, transferring cells from a first media to a second media to induce elongation of buds into shoots, harvesting and transferring shoots to a culture medium that promotes root development and culturing transferred shoots to produce plants (see columns 4-5). Though the amended claim has omitted introduction of exogenous DNA via particle bombardment, the cited reference still discloses the claimed method because the claimed method recites introducing exogenous DNA and does not state that particle bombardment cannot be used.

## Claim Rejections - 35 USC § 103

6. Claims 2-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al (Plant Cell Reports 15: 159-163, 1995), in view of Tegeder et al (Plant Cell Reports 15: 164-169, 1995), further in view of Weeks et al (Plant Physiol. 102: 1007-1084, 1993), still further in view of Cheng et al (Plant Physiol. 115: 971-980, 1997). The rejection is repeated for reasons of record as set forth in the Office Action mailed August 10, 2006 (see pages 3-5). Applicant's arguments, filed December 11, 2006, have been fully considered but are not persuasive.

Art Unit: 1638

Applicant argues that the previous Office Action fails to satisfy all three requirements for establishment of obviousness under 35 U.S.C. § 103 (see page 5, paragraph C of 'Remarks' filed December 11, 2006).

This is not persuasive. The Office Action mailed November 22, 2005, does satisfy all three requirements in that the combined references teach all the claim limitations, states the motivation in the references themselves and states that there is a reasonable expectation of success (see pages 5-7). Contrary to Applicant's assertion (see page 6, 1<sup>st</sup> paragraph of 'Remarks' filed December 11, 2006), the Zhou et al reference does teach culturing of explant in a bud inducing media.

Applicant argues that there is not motivation to combine the cytokinin media of Tegeder et al with the transformation methods of Zhou et al (see page 6, 2<sup>nd</sup> paragraph of 'Remarks' filed December 11, 2006).

This is not persuasive. The Tegeder et al reference teaches that media supplemented with cytokinin would result in shoot development; therefore, one of ordinary skill in the art would be motivated to use this teaching to promote shoot development in transformed plants.

Applicant argues that there would be no expectation of success in the combination of the references, in particular because Tegeder et al teach the use *Vicia faba* and Zhou et al teach transforming wheat (see page 6, 3<sup>rd</sup> paragraph of 'Remarks' filed December 11, 2006).

This is not persuasive. One of ordinary skill in the art would understand that different plants could be used with similar methods. There is no indication that the

Art Unit: 1638

teachings of Tegeder et al could not be used with wheat; therefore, one skilled in the art would understand to use the combined references.

Applicant argues that a greater than expected result is realized using the methods of the invention (see page 7, 1<sup>st</sup> full paragraph of 'Remarks' filed December 11, 2006).

This is not persuasive. The specification only shows greater than expected results using the cytokinin TDZ in combination with the multiple shoot inducing media MSIM12, MSIM13, MSIM15 and MSIM16 and not the broad genus of multiple bud inducing media in combination with the broad genus of cytokinins as is broadly claimed. See In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) where it states that evidence of superior properties in one species is insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds. See In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) where it states that one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way.

# Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Applicant's arguments with regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1-16 for lack of enablement will not be addressed in this Office Action because the rejection was withdrawn in the previous Office Action mailed August 10, 2006 (see page 2, paragraph # 3).

Art Unit: 1638

## Double Patenting

8. Claim 1 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,631,152. The rejection is repeated for reasons of record as set forth in the previous Office Action mailed November 22, 2005 (see pages 7-8).

Applicant argues that the previous Office Action has failed to set forth a *prima* facie case for obviousness type double patenting regarding claim 1 (see page 8, 2<sup>nd</sup> paragraph of 'Remarks' filed December 11, 2006).

This is not persuasive. The Examiner has fully explained the reasons for the rejection on page 8, paragraph # 10 of the Office Action mailed November 22, 2005. In addition, Applicant has not provided a timely filed terminal disclaimer to overcome the rejection.

## New Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1638

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fry et al (U.S. Patent 5,631,152, May 20, 1997), in view of Eudes et al (U.S. Patent 6,995,016, which is a continuation-in-part of application 09/641,243, filed August 17, 2000).

The claims read on a method of producing multiple transgenic wheat plants from a single explant comprising providing an explant presenting a plurality of meristems, culturing said explant in a first multiple bud inducing media suitable for inducing production of a plurality of buds from at least one of said meristems, introducing exogenous DNA into more than one of said plurality of buds, removing said plurality of buds from said first media and transferring said plurality of buds to a second media suitable for induction of elongation of said buds into shoots, harvesting and transferring said shoots to a culture medium that promotes root development and culturing said transferred shoots to produce multiple transgenic wheat plants.

Fry et al teach a method of producing multiple transgenic wheat plants from calli comprising culturing said calli on a nutrient media with carbohydrate and plant growth regulators (see column 3, lines 33-37).

Fry et al do teach immature caryopses collected from multiple plants which could be defined as explant presenting a plurality of meristems (see column 6, lines 20-21).

King et al (Dictionary of Genetics, 5<sup>th</sup> ed page 121) define an explant as "an excised"

Art Unit: 1638

fragment of a tissue or an organ used to initiate an *in vitro* culture"; therefore, one of ordinary skill in the art would understand that immature caryopses could be defined as explant.

Fry et al teach the culturing of calli on a modified MS medium wherein said medium consists of auxin (see column 3, lines 45-50) and one of ordinary skill in the art would be motivated to use media consisting of auxin because it is known in the art that auxin promotes growth and cell division. Thus, the method of Fry et al teaches inducing a plurality of buds.

Fry et al teach the introduction of exogenous DNA into embryogenic callus (see column 3, lines 64-65).

Fry et al teach removing the transformed embryogenic callus from the first media to a second media suitable for induction of the regenerable tissue into shoots (see column 4, lines 23-39).

Fry et al teach culturing the transformed shoots to produce multiple transgenic wheat plants (see column 4, lines 44-55).

Fry et al teach harvesting and transferring said shoots to a culture medium that promotes root development (see column 5, lines 21-22).

Fry et al teach the use of auxin (see column 3, lines 45-50).

Fry et al do not teach using cytokinins in a bud inducing media.

Eudes et al teach that the hormone content of the media is of greatest significance and that cytokinins, auxins and polyamines are major plant growth regulators used in tissue culture and that cytokinins are involved in tissue development

Art Unit: 1638

(see column 4, lines 51-54); therefore, one of ordinary skill in the art would understand that bud inducing media would comprise cytokinins and auxins.

With regards to claims 7-8, one of ordinary skill in the art would understand that different plant tissue could be used in the claimed invention and Fry et al teach, "[a]ny regenerable plant tissue can be used" (see column 3, lines 15-16).

With regards to claims 9-12 and 14-16, one of ordinary skill in the art would understand that various exogenous DNA could be used and that such DNA could be introduced by either particle bombardment of *Agrobacterium*-mediated transformation. In fact Fry et al teach "[the insertion of exogenous DNA in crop plants] has provided enormous opportunities to improve plant resistance to pests, diseases and herbicides" (see column 1, lines 12-14) in addition to teaching the use of transformation via the bombardment method (see column 3, lines 64-65).

With regards to claim 13, one of ordinary skill in the art would understand that compositions and concentrations of media could vary depending on the plants used.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Fry et al to develop a method for producing a transgenic wheat plant.

One of ordinary skill in the art would have be motivated to modify these teachings because Fry et al teach "[a]ny regenerable plant tissue can be used" (see column 3, lines 15-16); thus, one of ordinary skill in the art would be motivated to use explants from wheat based on the teachings Fry et al.

Application/Control Number: 10/064,001 Page 10

Art Unit: 1638

In addition, one of ordinary skill in the art would have a reasonable expectation of success based on the success of Fry et al.

#### Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D. January 26, 2007

DAVID H. KRUSE, PH.D. BRIMARY EXAMINER

m Muse